



## Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10757]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.
2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: CMS-P-0015A

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

*Contents*

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10757                      CLIA Collection of Information Requirements Related to SARS-CoV-2 Test  
Results Reporting

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of

information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### *Information Collection*

1. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting; *Use:* In order to be in compliance with the new CLIA mandatory SARS-CoV-2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920-1299) in order to collect laboratory data related to the COVID-19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory's compliance with the CLIA SARS-CoV-2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR §§493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required. *Form Number:* CMS-10757 (OMB control number: 0938-1391); *Frequency:* Daily; *Affected Public:* Private Sector Not-for-profit institutions and State, Local and Tribal Governments; *Number of Respondents:* 77,033; *Total Annual Responses:* 308,114; *Total Annual Hours:* 1,386,873 (For policy questions regarding this collection contact Sarah Bennett at 410-786-3354.)

Dated: April 8, 2021.

**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

[FR Doc. 2021-07559 Filed: 4/12/2021 8:45 am; Publication Date: 4/13/2021]